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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/886,349

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16May2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-19,70,72-75,83 and 85-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,70,72-75,83,85-88 is/are allowed.
- 6) ☒ Claim(s) 1,4 and 19 is/are rejected.
- 7) ☒ Claim(s) 2,3 and 7-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Office Action, received 16May2005, is acknowledged. Claims 5, 13, 72, and 83 have been amended.
2. claims 1-5, 7-19, 70, 72-75, 83, and 85-88 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 83 and 85-87 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of claim 83.
4. The rejection of claim 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 6,627,198 is withdrawn in light of the amendment of the claim.

Rejections Maintained

5. The rejection of claims 1, 4, and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 6,627,198 is maintained for reasons of record.

Applicants argue that instant claim one requires that "at least one amino acid corresponding to position 183 of SEQ ID NO:4 or position 208 of SEQ ID NO:2 in the MTB32A antigen (SEQ ID NO:2 or 4) has been substituted by a different amino acid." This limitation thus requires claim 1 to exclude SEQ ID NO:20 of U.S. Pat. No. 6,627,198.

The examiner has considered applicants' argument, but does not find it persuasive for claims 1, 4, and 19 which do not require SEQ ID NO:20.

Claim 1 of U.S. Pat. No. 6,627,198 recites: "A purified polypeptide **comprising** the amino acid sequence of SEQ ID NO:26".

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One of the embodiments of instant claim 1 is: "A composition **comprising** SEQ ID NO:12 or 14 or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and an immunogenic fragment of a MTB32A antigen (SEQ ID NO:2 or 4) from a *Mycobacterium* species of the tuberculosis complex." Since "an immunogenic fragment" is not restricted to size, the fragment can be ≥ 6 amino acids in length. Thus, because said substitutions listed in the claim occur at position 183 of SEQ ID NO:4 or position 208 of SEQ ID NO:2 or 4, and SEQ ID NO:2 is 355 amino acids in length and SEQ ID NO:4 is 330 amino acids in length, some of the fragments do not have to include the substitutions listed in the claim.

For example, one embodiment is a composition **comprising** the entire SEQ ID NO:14 of MTB39 antigen and an immunogenic fragment of SEQ ID NO:4 (residues 8-182). This corresponds to SEQ ID NO:26 residues 9-399 and residues 402-575.

A second embodiment is a composition **comprising** the entire SEQ ID NO:14 of MTB39 antigen and an immunogenic fragment of SEQ ID NO:2 (residues 32-207). This corresponds to SEQ ID NO:26 residues 9-399 and residues 402-576.

6. The objection to claims 2, 3, and 7-18 due to dependence from rejected claims is maintained for reasons of record.

The claims remain dependent from rejected claims 1 and 4.

Conclusion

7. Claims 1, 4, and 19 are finally rejected. Claims 2, 3, and 7-18 are finally objected to for improper dependency. Claims 5, 70, 72-75, 83, and 85-88 appear to be allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Rodney P. Swartz". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

RODNEY P. SWARTZ, PH.D

PRIMARY EXAMINER

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July 11, 2005